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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,341	10/25/2001	Bradley Stuart Galer	1203-01	3845
35811	7590	01/21/2005	EXAMINER OH, SIMON J	
IP GROUP OF DLA PIPER RUDNICK GRAY CARY US LLP 1650 MARKET ST SUITE 4900 PHILADELPHIA, PA 19103			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,341

Applicant(s)

GALER, BRADLEY STUART

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-19 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 8-19 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's response, information disclosure statement, petition for extension of time, and request for continued examination, all received on 29 December 2004.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1 and 8-18 under 35 U.S.C. 103(a) as being unpatentable over Hind in view of Rolf *et al.* is maintained.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hind in view of Rolf *et al.*

The Hind patent teaches methods and compositions for reducing pain from shingles by topical administration of lidocaine at a dosage below that which achieves analgesia without inducing anesthesia or systemic side effects (See Column 3, Lines 1-17 and 29-36). In the disclosed compositions, lidocaine is present in amounts of about 1 to 25% by weight (See Column 3, Lines 55-65). Included in the disclosure are details of a study in which patches containing 5% lidocaine as well as other excipients are administered to patients. The patches are applied to areas of greatest pain, up to 12 hours (See Column 15, Lines 11-39).

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Hind does not indicate that the disclosed compositions and methods can be used to treat pain from the group consisting of myofascial pains, fibromyalgia, bursitis, costochondritis, repetitive motion injuries, carpal tunnel syndrome, and nociceptive pain.

The Rolf *et al.* patent teaches an analgesic adhesive patch that can be used to treat arthritis, backache, muscular aches, and strains. Lidocaine is listed among the active ingredients suitable for use in the disclosed patch (See Claims 1 and 3).

It would be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hind and Rolf *et al.* into the objects of the instant application. The teachings of Hind provide for topical lidocaine compositions and methods to treat pain in a way that produces analgesia without causing anesthesia. The teachings of Rolf *et al.* disclose that, in one embodiment, an analgesic patch comprising lidocaine can be used in the treatment of pain caused by arthritis, backache, muscular aches, and strains, which are all known to be various types of nociceptive pain. It is the position of the examiner that one of ordinary skill in the art, at the time the claimed invention was made, would observe the structural similarity of the compositions disclosed in the prior art references, and would thus be motivated to use the compositions and methods of treatment of Hind to relieve pain stemming from the conditions described in Rolf *et al.* One of ordinary skill in the art would have a reasonable expectation of success that the compositions and methods of the combined disclosure of the prior art would allow for the use a patch comprising lidocaine in a concentration that induces analgesia, rather than anesthesia, for the treatment of both nociceptive pain and neuropathic pain.

Thus, the claimed invention as a whole is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 29 December 2004 have been fully considered but they are not found to be entirely persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The applicants have acknowledged that the disclosure of the Hind patent teaches the relief of pain by the use of lidocaine at concentrations that achieve analgesia without inducing anesthesia. However, the applicants have not acknowledged significant disclosures in Hind, particularly the concept that in the aim of achieving analgesia without inducing anesthesia, concentrations of lidocaine are not restricted only to the range of 4%-6%. The Hind patent discloses that the concentration in plasters usually range from about 2-10% (See Column 3, Lines 55-65).

The differences between neuropathic and non-neuropathic pain are understood and respected by the examiner. However, the examiner still maintains the previously held position that the prior art makes obvious the instantly claimed invention. The passage in the Rolf *et al.* patent cited by the applicant in the response is, in the view of the examiner, not a strict statement of the particular function of lidocaine within the disclosed invention, but rather it is a broad category of active agents to which lidocaine belongs. The examiner interprets this passage to mean that although lidocaine is broadly categorized as an anesthetic agent, it is used in the disclosed invention as an analgesic. Thus, it adds to the teachings of Hind in that lidocaine may

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be used in the analgesic treatment of pain. Furthermore, the 8% concentration of lidocaine disclosed in Rolf *et al.* and cited by the applicant in the response is considered by the examiner to lend further credence to the examiner's interpretation of the passage in Rolf *et al.* cited by the applicant. As Hind has disclosed, concentrations ranging from about 1% to 25% and preferably 2% to 10% may be used to achieve an analgesic effect using lidocaine.

As such, the pending claims remain obvious in view of the prior art.

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Correspondence

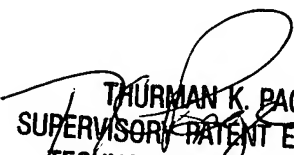
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
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sj0


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600